

**Amendments To The Drawings:**

Please amend figure 9 to illustrate a guide wire 92 extending through the guide wire channel.

Please also amend Figure 8 by replacing reference numeral 95 with reference numeral 85.

A replacement sheet is included herewith.

**Remarks**

This Amendment After Final is in response to the Final Office Action dated

**December 8, 2009.**

***Drawings***

In the Final Office Action, the drawings have been objected to:

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “first layer is an outer layer and the second layer is an inner layer” and “a guidewire extending through said lumen” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Figure 9 has been amended to illustrate a guide wire 92 extending through guide wire channel 85.

Figure 8 has been amended to correct a typographical error. Reference numeral 95 referring to the guide wire channel has been replaced with reference numeral 85 in accordance with Figure 9.

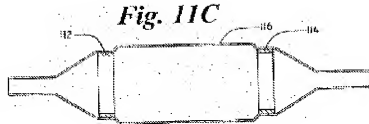
Please note that the embodiment of claim 1, wherein a guide wire is recited, does not refer to a first layer and a second layer.

The paragraphs of the specification beginning on page 16, line 10 to page 17, line 6 have also been amended. Both reference numeral 95 and reference numeral 85 had been used to refer to the guide wire channel. Applicants have also amended these paragraphs to include reference to a guide wire 92 now shown in Figure 9.

No new matter has been added.

Please note that a first polymer layer and a second polymer layer as recited in the embodiment in independent claim 32, for example, are already shown in the drawings, cf. figure

11C, and are discussed in the description of figures 11A-11C in the specification. Figure 11C and the corresponding description are reproduced below:



Figures 11A-C illustrate yet another embodiment of the invention. In Fig. 11A, a basic balloon form 110 of ice or other fluidizable solid is shown. To the form 110 have been applied circumferential bands 112 and 114. The bands 112 and 114 are elastic materials which have been stretched from their rest diameter to reach their diameter on the form. The elastic material may be silicone or other rubbery material, but is one to which the cured polymer film formed of the curable composition will adhere. The curable composition 116 is then applied by spray or other technique, over the entire form, including over the bands 112 and 114, as shown in Fig 11B, and then cured to form a balloon with the bands 112 and 114 embedded therein. In Figure 11C, when the fluidizable form has been removed, the composite balloon is stressed by the bands 112, 114 to collapse to their rest position. This aids in obtaining a small deflated profile. Bands placed as depicted here, or in other configurations may also be used to alter balloon distension curves.

Specification, p. 17, line 32 – p. 18, line 11

Applicants have amended the above paragraph to clarify that the bands 112, 114 are applied as a first polymer layer and the curable composition is applied as a second polymer layer in accordance with the embodiment recited in claim 32. No new matter has been added.

Please note, there is no guide wire recited in the embodiment in claim 32 wherein first and second polymer layers are recited.

Withdrawal of the objections to the drawings is respectfully requested.

***Rejections - 35 U.S.C. §102(b)***

The rejection of claims 32-36 under 35 U.S.C. §102(b) as being anticipated by Shaffer et al. (USPN5,049,132) has been maintained.

It is asserted in the Final Office Action, Response to Arguments, that:

Regarding the Shaffer et al. (USPN5,049,132) reference, the Examiner asserts the claim scope only requires the layers to be “in adherent contact” or connected, coupled or attached to each other. The first and second layers (44 and 16) are connected to each other via the posts (50) and are adhered to each other by these posts along the length of the layers. The Examiner does not consider the claim scope to cover layers that each have an inner and outer surface directly bonded to each other over the entire length thereof.

Final Office Action, page 8, last par.

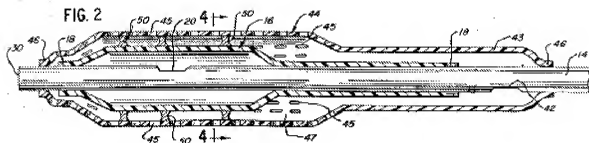
Applicants disagree.

Applicants submit that the recitation in claim 32 “... said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces ...” is sufficient to distinguish over the layers of Shaffer et al. wherein each layer is in contact with a post, but is not in adherent contact with each other. Furthermore, the recitation of “in adherent contact” is not equivalent to the terms connected, coupled or attached to.

Nonetheless, for purposes of expediting prosecution, Applicants have amended claim 32 to recite “directly bonded” as proposed in the Final Office Action. This is seen as being a non-substantive amendment and Applicants respectfully request that as such, it being entered after Final.

No new matter has been added.

Clearly, layers 16, 44 are not directly bonded to each other but rather are separated by posts 50, cf. Figure 2 of Shaffer et al. reproduced below:



Claim 32 is therefore not anticipated by Shaffer et al.

Claims 33-36 depend from claim 32 and are not anticipated by Shaffer et al. for at least the reasons that claim 32 is not anticipated by Shaffer et al.

Withdrawal of the rejection of claims 32-36 under 35 U.S.C. 102(b) as being anticipated by Shaffer et al. (USPN5,049,132) is respectfully requested.

#### ***Rejections – 35 U.S.C. §102(e)***

The rejection of claims 32, 36-38, 65, and 69-70 under 35 U.S.C. §102(e) as being anticipated by Steadham et al. (USPN 7,331,933) has been maintained. It is asserted in the Final Office Action “Steadham et al. discloses a balloon with compression member.”

While this may be somewhat true, the disclosure of such is not sufficient to anticipate independent claim 32.

Independent claim 32 recites an article including, inter alia, at least first and second layers, each layer having an inner and an outer surface, the first and second layers being directly bonded to each other over a coextensive area along respective outer and inner surfaces. Each of the first and second layers having an at-rest configuration defining wherein the at-rest area of the first layer outer surface is smaller than the at-rest area of the second layer inner surface. The at-rest configuration is the configuration the respective outer and inner surfaces would adopt when

unstressed. Because coextensive layers of the balloon have different at-rest areas, the interface between the balloon layers is necessarily stressed even when the balloon is uninflated and at ambient pressure.

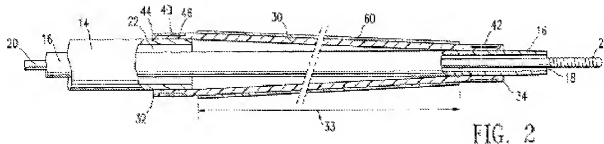
Steadham et al., in contrast, is not under stress in its at-rest configuration.

Steadham et al. in fact disclose with respect to the compression bands, the following:

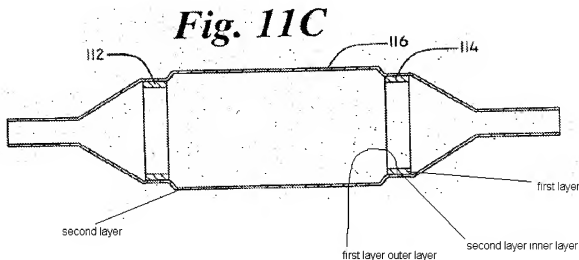
In the embodiment illustrated in FIG. 1, a proximal compression member 40 and a distal compression member 42 sealingly secure the balloon 30 to the outer tubular member 14 and the inner tubular member 16, respectively. The compression members 40, 42 are bands with a first outer diameter that allow the bands to be placed around an outer surface of the balloon and which contracts to a second, smaller diameter which then secures the balloon 30 to the shaft 12. In one embodiment, compression members 40, 42 are radiopaque marker bands. FIGS. 1 and 2 also illustrates an outer diameter around the circumference the compression members 40, 42 which is not greater than the outer diameter of a first portion 44 of the skirt section 32 directly adjacent to a second portion 46 of the skirt section about which the compression member is mounted. However, in an alternative embodiment, the compression members 40, 42 may have an outer diameter, which is greater than the outer diameter of the directly adjacent portion of the balloon.

Detailed Description, 3<sup>rd</sup> paragraph (emphasis added)

The statement that the compression members 40, 42 have a diameter which is not greater than the outer diameter of a first portion 44, is not a disclosure of the compression members 40, 42 having an outer surface with an area that is less than the inner surface diameter of the first portion 44 in an at-rest configuration. In the at-rest configuration, the disclosure is simply that the diameter of the compression members 40, 42 is not greater than that of the first portion 44. For convenience, please refer to FIG. 2 reproduced below:



Furthermore, in the embodiment above, the at-rest area of the first layer outer surface is not smaller than the at-rest area of the second layer inner surface. FIG. 11C of the present invention has been reproduced below to illustrate this embodiment:



If anything, it would be the opposite of the above. However, Applicants submit that in an at-rest configuration, Steadham et al. simply lack any disclosure that the area of the compression band in contact with portion 44 is smaller and under stress.

Claim 32 is not anticipated by Steadham et al.

Claims 36-38 and 69-70 depend from claim 32 and are not anticipated by Steadham et al. for at least these reasons.

Claim 65 recites a balloon including, inter alia, a balloon body having a proximal

end and a distal end, and the balloon comprising circumferential elastic bands on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

Claim 65 is also not anticipated by Steadham et al. As discussed above, there is no specific disclosure by Steadham et al. that the compression bands have a smaller diameter than the portion 44 in their at-rest configuration. Perhaps in an expanded configuration, but not when they are at-rest.

Withdrawal of the rejection of claims 32, 36-38, 65, and 69-70 under 35 U.S.C. §102(c) as being anticipated by Steadham et al. (USPN 7,331,933) is respectfully requested.

***Rejections – 35 U.S.C. §103(a)***

**Claims 27-28 and 63-64**

Claims 27-28 and 63-64 are rejected under 35 U.S.C. §103(a) as being obvious over Anderson (USPN 6,007,517) in view of Yang et al. (US2001/0003796).

It is asserted in the Final Office Action that “Anderson as modified by Yang et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.” Final Office Action, page 8, last paragraph.

Independent claims 27 and 63 recite, inter alia, a medical balloon formed of a radiation cured polymerizable composition, wherein the balloon comprises a lumen offset from the longitudinal axis, the lumen passing through the tapering proximal and distal wall portions of the balloon and a guidewire extending through said lumen.

Applicants traverse the rejection.



Anderson fail to disclose or suggest a balloon formed from a radiation polymerizable composition.

Yang et al. also fail to disclose or suggest a balloon formed from a radiation polymerizable composition.

Yang et al. disclose a balloon coated with a hydrogel coating which is a high molecular weight polyethylene oxide coating and 2,2'-azobis isobutyro-nitrile catalyst which is subsequently dried and cured under UV radiation.

The balloon itself is not formed from such a material.

No *prima facie* showing of obviousness has been made with respect to claims 27 and 63 because the combination fails to disclose or suggest all of the elements of the claim. *Prima facie* obviousness requires that the prior art reference (or references when combined) teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

Claims 28 and 64 depend from claims 27 and 63 respectively and are not obvious over Anderson in view of Yang et al. for at least these reasons.

Withdrawal of the rejection of claims 27-28 and 63-64 under 35 U.S.C. §103(a) as being obvious over Anderson (USPN 6,007,517) in view of Yang et al. (US2001/0003796) is respectfully requested.

#### **Claims 66-68**

Claims 66-68 are rejected under 35 U.S.C §103(a) as being obvious over Steadham et al. (USPN 7,331 933) in view of Crocker et al. (USPN 6,120,523). It is asserted in the Final Office Action that “Steadham meets the claim limitations as described above except for

the bands being located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition. However, Crocker et al. teaches a focalized intraluminal balloon.”  
Final Office Action, pp. 6-7.

Applicants traverse the rejection.

Claims 66-68 depend from claim 65.

Claim 65 has been discussed above and recites a balloon including, inter alia, a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

The disclosure of Steadham et al. is as follows:

In the embodiment illustrated in FIG. 1, a proximal compression member 40 and a distal compression member 42 sealingly secure the balloon 30 to the outer tubular member 14 and the inner tubular member 16, respectively. The compression members 40, 42 are bands with a first outer diameter that allow the bands to be placed around an outer surface of the balloon and which contracts to a second, smaller diameter which then secures the balloon 30 to the shaft 12. In one embodiment, compression members 40, 42 are radiopaque marker bands. FIGS. 1 and 2 also illustrates an outer diameter around the circumference the compression members 40, 42 which is not greater than the outer diameter of a first portion 44 of the skirt section 32 directly adjacent to a second portion 46 of the skirt section about which the compression member is mounted. However, in an alternative embodiment, the compression members 40, 42 may have an outer diameter, which is greater than the outer diameter of the directly adjacent portion of the balloon.

Detailed Description, 3<sup>rd</sup> paragraph (emphasis added)

Claim 65 is not obvious over Steadham et al. As discussed above, there is no specific disclosure by Steadham et al. that the compression bands have a smaller diameter than the portion 44 in their at-rest configuration. Perhaps in an expanded configuration, but not when they are at-rest.

Combining a focalized intraluminal balloon with Steadham et al. still fails to render

claim 65 obvious.

Claims 66-68 are not obvious over Steadham et al. in view of Crocker et al. for at least these reasons.

Withdrawal of the rejection of claims 66-68 under 35 U.S.C §103(a) as being obvious over Steadham et al. (USPN 7,331 933) in view of Crocker et al. (USPN 6,120,523) is respectfully requested.

**Claims 30-31**

Claims 30-31 are rejected under 35 U.S.C. §103(a) as being obvious over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796). It is asserted in the Final Office Action that “Anderson as modified by Yang et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.” Final Office Action, page 7.

Applicants traverse the rejection.

Claims 30 and 31 depend from claim 27.

Claim 27 has been discussed above with respect to Anderson and Yang et al.

Claims 27 recites, inter alia, a medical balloon formed of a radiation cured polymerizable composition, wherein the balloon comprises a lumen offset from the longitudinal axis, the lumen passing through the tapering proximal and distal wall portions of the balloon and a guidewire extending through said lumen.

Anderson fail to disclose or suggest a balloon formed from a radiation polymerizable composition.

Yang et al. also fail to disclose or suggest a balloon formed from a radiation polymerizable composition.

Yang et al. disclose a balloon coated with a hydrogel coating which is a high molecular weight polyethylene oxide coating and 2,2'-azobis isobutyro-nitrile catalyst which is subsequently dried and cured under UV radiation.

The balloon itself is not formed from such a material.

No *prima facie* showing of obviousness has been made with respect to claims 27 because the combination fails to disclose or suggest all of the elements of the claim. *Prima facie* obviousness requires that the prior art reference (or references when combined) teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

Claims 30 and 31 are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 30 and 31 under 35 U.S.C. §103(a) as being obvious over Anderson (USPN 6,007,517) in view of Yang et al. (US 2001/0003796) is respectfully requested.

**CONCLUSION**

Claims 27, 28, 30-38 and 63-70 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 5, 2010

By: /Lisa Ryan-Lindquist/  
Lisa R. Lindquist  
Registration No.: 43071

6640 Shady Oak Rd., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001